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Award Number: DAMD17-01-1-0078

TITLE: Study of prostate cancer screening and mortality in black and white men in the five Atlanta area SEER counties

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CONTRACTING ORGANIZATION: Morehouse School of Medicine Atlanta, Georgia 30310-1495

REPORT DATE: October 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

reviewing this collection of information. Send comme Information Operations and Reports, 1215 Jefferson I	nts regarding this burden estimate or any othe	r aspect of this collection of informa	tion, including suggesti	maintaining the dons for reducing this burden to Washington Headqua perwork Reduction Project (0704-0188), Washington
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND	DATES COVER	ED
4. TITLE AND SUBTITLE Study of prostate cancer screening a Atlanta area SEER counties	October 2002 and mortality in black and whit		5. FUNDING I DAMD17-01-1	
6.AUTHOR(S) Nabih R. Asal, Ph.D).			
7. PERFORMING ORGANIZATION NAM	ME(S) AND ADDRESS(ES)		8. PERFORMIN REPORT NU	IG ORGANIZATION
Morehouse School of Atlanta, Georgia 30 email - asaln@mdm.ed	310-1495			
9. SPONSORING / MONITORING AGE	NCY NAME(S) AND ADDRESS(E	S)		ING / MONITORING
U.S. Army Medical Research and N Fort Detrick, Maryland 21702-501			AGENCY I	REPORT NUMBER
11. SUPPLEMENTARY NOTES			<u></u>	
12a. DISTRIBUTION / AVAILABILITY S Approved for Public Rele		limited		12b. DISTRIBUTION CODE
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13. ABSTRACT (Maximum 200 Words	•			<u> </u>
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14. SUBJECT TERMS prostate cancer, black a	and white men			15. NUMBER OF PAGES 35
17. SECURITY CLASSIFICATION 1: OF REPORT Unclassified	B. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSII OF ABSTRACT	FICATION	16. PRICE CODE 20. LIMITATION OF ABSTRACT Unlimited
Unclassified NSN 7540-01-280-5500	Unclassified	Unclassif	L	idard Form 298 (Rev. 2-89)

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Study of Prostate Cancer Screening and Mortality Among Black and White Men In the Five Atlanta Area SEER Counties

I. Introduction

Prostate cancer is the leading cause of cancer morbidity and the second leading cause of cancer mortality among U.S. men, and is projected to account for an estimated 189,000 (30%) new cases and 30,300 (11%) deaths in the year 2002 (1). The significant decreases in mortality and incidence that occurred since 1992 and have continued to the present, primarily among white men, have been attributed to increased awareness of the disease and efforts in early detection. African American men have the highest incidence and mortality rates in the world and continue to experience significantly higher incidence and twice as high death rates as whites in the U.S. The disparity in morbidity and mortality between African American and white men in the U.S. has not been adequately studied or explained, although it is generally believed that a number of factors are responsible, including stage at time of diagnosis and accessibility to health care (1).

There is a great deal of controversy surrounding the interpretation of existing epidemiological and clinical evidence. Expert groups recommendations regarding the age, frequency and the necessity for the use of the Prostate Specific Antigen (PSA) and the Digital Rectal Examination (DRE) for mass screening in the general population as a public health policy remain conflicting and controversial. Results from large scale randomized controlled trials conducted by the National Cancer Institute and the European Union, necessary to document the benefits of screening through reduction in mortality, will be available in few years. Meanwhile, a number of case-controlled studies, including the present study, are underway to determine if screening with the PSA and DRE reduce mortality from Prostate Cancer.

II. Body

Objectives/Hypothesis: the objectives of this study is to provide much needed data on the efficacy of screening for prostate cancer using observational case-control methodology while awaiting the results of randomized controlled trials and to explain the black white disparity in mortality from prostate cancer. The hypothesis to be tested is that the frequency of screening tests (PSA and DRE) should be higher in the general population, as represented by a control group, than in the group of men who die from prostate cancer.

Specific Aim: Is to determine if screening with the PSA and DRE reduces mortality from prostate cancer.

Study Design: To accomplish this aim and test the hypothesis, a case-control study was planned and is being conducted in the 5 SEER Atlanta Georgia counties with access to or with an automated linkage to death certificates. The frequency of PSA and DRE screening prior to the diagnosis of prostate cancer will be compared between a sample of 450 men (170black& 280 white) who died from prostate cancer in the five counties during the 2-4 year 1998-2001 period and a sample of 450 control men (170black and 280 white) who did not die from prostate cancer. Deaths will be ascertained directly from the SEER Registry and the Georgia Department of Public Health. The hospital based cases and controls will be frequency matched by race, age, sex, and county of residence.

Death records will be systematically linked to hospital records using seven identifiers: name, Social security #, date of birth or age, date of death, race, and county of death and residence. Hospital, physician and laboratory records will be reviewed to assess the frequency of DRE and PSA tests in cases and controls for a period of 12 to 14 years prior to the date of death of the case and to include the exposure period prior to the reference date of diagnosis of the case.

The Odds Ratio with 95% C.I. will be used for overall comparisons and within subgroups defined by risk factors and adjusted for co-morbidity. Logistic regression will be used to generate summary odds ratios adjusted for Co-variates.

III. Key Research Accomplishments

Key research accomplishments are based on progress made relative to each of the items listed under Tasks 1-5 in the Statement of Work that follows and submitted as part of the Proposal.

Statement of Work

Task 1. Personnel Recruitment/Arrangements, Months 1-4:

a. Prepare paper work, position description and advertisement.

Completed in a timely fashion.

b. Hire and train data abstractor(s).

- Two key personnel were hired on the Project. Yassa Nadjakani, M.D., M.P.H. was hired as Project Coordinator on October 1, 2001 and C elestine Kiki, M.D., M.P.H. was hired as Post doctoral Fellow on November 5, 2001. Both are involved with the Principal Investigator in all aspects of the project including IRB approval and Hospital arrangements, form development, abstracting and data collection. There remains open the positions of Data Abstractor and One Post Doctoral Fellow. These will be filled as needed. A Report on Dr. Kiki'e Progress to date as a Post Doctoral Fellow appears in Appendix B.
 - c. Finalize arrangements with Tumor Registries, the Health Departments, Hospitals, Laboratories, Urologists, and Primary Care Providers.

Arrangements have been made and completed with the Tumor Registries at the Georgia Department of Human Resources and the Georgia Cancer Registry which includes the NCI sponsored SEER Registry. Arrangements have also been made with all the hospitals in the Metropolitan Atlanta which admit residents from the 5 SEER Counties of Clayton, Cobb, Dekalb, Fulton, and Gwinnett. It is too early to begin to contact laboratories, urologists and primary care providers. This process bein once cases and controls have been identified and their medical charts abstracted.

d. Obtain death certificates lists and all other materials from the State Health Departments and Tumor Registries.

Listing of all prostate cancer deaths have been obtained from the Georgia Department of Human Resources and the Georgia Cancer Registry that includes the SEER Registry for the years 1998, 1999, and 2000. Data for the year 2001 is forthcoming and has not been available yet.

Task 2. Sample Size Determination and Power Calculations, Months 1-4:

a. Review Georgia State Department of Health mortality records and registry data for 1999-2000 (expanded to include 1998-2001) to determine the number of men dying from prostate cancer.

The following table summarizes the prostate cancer mortality data obtained from the Georgia Department of Human Resources and the Georgia Cancer Registry. We expanded the initial 2 year period 1999-2000 to the four year period 1998-2001 to assure adequate sample size.

Table 1
Prostate Cancer Mortality in the 5 Metro Atlanta SEER Counties
1998, 1999, 2000, 2001*
By Race

Counties	1998 Black	White	19 Black	99 White	2 Black	000 White	20 Black	001 White	1	otals White	Grand Totals
Clayton	4	11	4	1	1	4			9	16	25
Cobb	3	33	6	21	5	26			14	80	94
Dekalb	24	32	17	22	17	27			58	81	139
Fulton	58	33	57	45	19	20		1 20 20 20 20 20 20 20 20 20 20 20 20 20	134	98	223
Gwinnett	1	23	3	26	2	21			6	70	76
Totals	90	132	87	115	44	98			221	345	566

^{*} Data for 2001 will be provided soon

The 221 black deaths and 345 white deaths exceed the needed sample of 170 blacks and 280 whites projected for adequate power.

b. Determine the adequacy of sample size projected in the proposal.

The Sample size of 450 men 170 black and 280 white appear adequate at this time. Inclusion of 2001 death will provide additional 35-40 blacks and 80-90 white deaths.

- Task 3. Modify and Pre-test Medical Record Review Form, Months 2-4:
 - a. Modify, pretest, refine and finalize the medical record review forms found in the appendix.

The Medical Record Review forms developed, pretested and used in the Carolina Prostate Cancer Screening Study (CPCSS) n which is funded by the American Cancer Society and being conducted by Paul Godley of the University of North Carolina Division of Hematology and Oncology has been adopted by this project, slightly modified and used. See Form in Appendix A.

b. IRB packages will include the final medical record review forms and protocol with sampling and data collection strategies and final sample size estimates.

IRB approval has been obtained from almost all of the participating hospitals with the exception of Northside hospital were access to medical records has been denied. Table 2 provides the detailed information regarding the Hospital/INstitutional IRB approval process and status:

Table 2
Study of Prostate Cancer Screening and Mortality In Black and White
Men in Five Atlanta Area SEER Counties
Hospital/Institutional IRB Approval Status

Hospital/ Institution	Telephone	IRB Contact	IRB Status	Date Approved
Morehouse School of Medicine	404-752-1973 404-752-1711	John Smith, M S W Ralph Trottier, PhD, JI	Approved)	11/16/2000 Revised 1/23/2001
Georgia Departmer Human Resources	nt404-657-1453 404-657-5254	Margaret Palli Exec. Sec. Allan Goldman, member	Approved Incorporated changes in Consent Form	2/20/2001 Revised Letter received 8/9/2001
US Army M.R.M. Command	301-619-6987	Maryann Pranulis		Grant Awarded 9/24/2001
V.A.M.C.	404–321-6111 X2512	Emory HIC Matthew Howard	Approved/ Emory Submitted 8/7/01 8/16/01 (directly)	8/15/2001 letter received 12/6/01
Crawford Long Hosp.	404-727-5646 Dr. Bennett (Local) Special Forms	Emory HIC	Approved/Emory. Submitted 8/7/01	8/15/2001 letter received 12/6/01
Cobb Hospital & Med Center	770-732-4000 770-739-3495	Accepts MSM IRB Approval	Approved Submitted letter 8/8/01 to access	11/16/2000 Revised 1/23/2001
Decatur Hospital	404-501-6100 Richard Schmidt Exec. Director	Accepts Dekalb Med Center IRB Approval	Approved Submitted 8/23/01	9/07/2001
Dekalb Med Center	404-501-1000 Special Forms(7:00) Local Investigator	Robert C. Jerris, PhD Chair, IRB	Approved Submitted 8/23/01	9/07/2001
Emory Univ Hospital	404-727-5646 Local Investigator	Emory HIC www.Emory.Edu/WHS C/MED/HIC	Approved Submitted 8/7/01	8/15/2001 Letter received 12/6/01

Atlanta Med Center	404-265-3592 local Investigator	Carol Ehlban Dr. Saltzman, IRB Chair	Approved Submitted 8/8/01 to acces	11/8/2001 swith 4 specifications
Grady H.S.	404-616-4360 Local Investigator Dr. Bennett	Accepts MSM	Approved Submitted 8/8/01; Approv on 10/2/2001	11/16/2000 aRevised 1/23/2001
Gwinett Med Cente	r 678-442-3288 Local Investigator	Polly Dormyny	Not submitted	To mail list of Urologists
Kennestone Hospit	a(770)732-4152	Andrea Parson Accepts MSM	Approved Submitted letter 8/8/01 to access	11/16/2000 Revised 1/23/2001
Northside Hospital	(404) 851-6848 NSH 612 Special forms Local Investigator	Shirley S. Elks IRB Data Manager	Denied Approval Submitted 8/7/01 Review 8/28/01	
Piedmont Hospital	(404)605-3638 Submit 4 copies on 9/18/01 for 10/9/01	Emmy Jansen IRB meets quarterly 10/9/2001 meeting	Approved. Submitted 8/14/01	10/9/2001 for one year
St Joseph's hospita	l (404)851-5615 Local Investigator	Magi Riley Need full proposal	Approved. Submitted 8/8/01	12/17/01 for one year, letter date 12/18/01
Shepherd Center	404-352-2020 Dr. Bennett	9/13	Approved. Submitted 8/9/01	10/15/2001 subject receipt n-o-k In.Consen
South Fulton Med Center	404-305-4571	Vicky Blound. Accepts MSM	Approved Submitted letter 8/16/01 to access	11/16/2000 Revised 1/23/2001
Southern Regional Med Center	(770)-991-8334 Require Active Medical Staff Co-Investigator/Sponsor		Pending IRB App. Submitted 8/15/01	Co-Investigators agree to participate. Awaiting identification of subjects from death records
Wellstar Kennestor	e(770)732-4152	Accepts MSM IRB	Approved MSM Submitted letter 8/9/01	11/16/2000 Revised 1/23/2001

Task 4. Access Hospital Lists/Select Controls, Months 4-6:

a. Identify list of hospitals where cases were diagnosed.

Table 3 provides a summary of all participating hospitals and numbers of cases that have been availed and/or abstracted.

Table 3 Study of Prostate Cancer Screening and Mortality In Black and White Men In Five Atlanta Area SEER Counties Medical Record Abstracting of Cases Progress Report October 20, 2002

Hospital	# of Charts Reviewed	Charts Reviewed Blacks	Charts Reviewed Whites	Number of Charts Requested	Number of Charts Pending Review	Estimated Total Number of Charts
V.A. M.C.	ASAP					

Crawford Long Hosp	; 13	10	3	16	28	60
Cobb Hospital						
Decatur Hospital						
Dekalb Med Center	7	3	4	27		34
Emory University Hospital	49	4	45			49
Atlanta Medica Center	ıl					
Grady H.S.	45	44	1	10		55
Gwinett Medical Center						
Kennestone Hospital						
Northside Hospital						
Piedmont Hospital	5	1	4	17		21
St. Joseph Hospital	ASAP					
Shepherd Center						
South Fulton Med Cntr						
Southern Regional Medical Cente						
Wellstar Kennestone						
Totals	119	62	57	70	28	219

b. Finalize arrangements with hospitals for in-site visit.

See Tables 2 and 3 above.

c. Selection of Controls at each hospital.

- Not completed, awaits completion of case accrual and abstracting before selection of controls begins
 - Task 5: Conduct Medical Record Review/Computerize Data Set for Analysis, Months 6-30:
 - a. Begin data collection on cases and controls from hospitals, physicians and laboratories.

Work in Progress. Please see Table 3.

b. Conduct the medical record review on 450 black and white males prostate cancer deceased cases and their 450 frequency matched age and race male controls.

Work in Progress. Please see tables 3.

c. Ongoing quality control, cleaning and completeness of data.

A sub set of the data abstracted by Dr. Kiki has been re-abstracted by Dr. Nadjakani for quality control. Differences, when noted have been discussed and the data corrected when appropriate. Further, Information abstracted by the Tumor Registry Personnel on prostate cancer cases is being reviewed and serves as a quality control on our own abstracting and providing a useful source to obtain missing information.

d. Computerize completed, cleaned, and validated data and translate into ASCII file format with a data dictionary.

Not applicable.

Task 6. Data Analysis, Months 30-33:

a. Comprehensive analyses of collected data according to statistical procedures outlined in the statistical section of the proposal.

Not Applicable

Task 7. Final Report/Manuscript Preparation, Months 33-36:

a. Preparation of the final report to funding agency and manuscript prepared for publication.

Not Applicable

IV. Reportable Outcomes

Work In Progress no Outcomes to Report.

V. Conclusions

Study is progressing as planned. Only one post doctoral fellow was hired, she and the project director are performing, in part, duties other wise performed by the abstractor.

The Principal Investigator has relocated to the University of Florida at Gainesville. He continues to retain Adjunct Affiliation with Morehouse School of Medicine where the Study is currently housed. The P.I. maintains daily contact with staff through e-mail and telephone exchanges and travels almost weekly to Atlanta and Morehouse School of Medicine to attend to Project needs.

The Principal Investigator plans to expand the Geographic area of the study to include in addition to the 5 Metro Atlanta Counties,23 counties in North Central Florida, that demographically include is diverse population of blacks, whites, rural and urban residents.

IRB approval has been obtained from the University of Florida Health Sciences Center that covers the Shands Health System in North Central Floprida that includes the University of Florida Campuses in Gainesville and Jacksonville. The Chief of the Division of Urology at the University of Florida has agreed to join the project as Co-investigator and has agreed to provide both the urologic expertise and contacts with urologists in North Central Florida. The Florida Department of Health has agreed to provide all needed mortality records. The Florida State Tumor Registry will provide access to any and all prostate cancer data that has already been collected.

The Principal Investigator is currently engaged with Morehouse School of Medicine Administrators and the funding agency in discussions to either transfer the project to the University of Florida and provide Morehouse School of Medicine a subcontract or to leave the Project

• at Morehouse School of Medicine and provide the University of Florida a Subcontract. The Executive Dean at Morehouse School of Medicine, E. Nigel Harris, has already provided a letter supporting the transfer of the project to the University of Florida.

VI. References

1. American Cancer Society Facts and Figure, 2002, ACS, Atlanta, Georgia

VII. Appendices

Appendix A: Study of Prostate Cancer Screening and Mortality: Medical Records Abstract Form

Appendix B: Progress Report, Celestine Kiki, M.D., M.P.H., Post Doctoral Fellow

Appendix A

Study of Prostate Cancer Screening and Mortality in Black and White Men

Nabih R. Asal, Ph.D., Principal Investigator

Medical Record Abstract Form

PD St	udy Medica	l Record	#:					
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PROSTATE CANCER DISEASE STUDY CHART REVIEW FORM

REVIEWER_		-	
LAST NAME	B:		
FIRST NAM	E:		MIDDLE INITIAL:
BIRTH DAT	E (mm/	/dd/yyyy):/	
INDEX PRO	STATE	E CANCER DIAGNOSIS DATE (mm/dd/yy):	/ 19
DATE 12 MO	ONTHS	S PRIOR TO DIAGNOSIS (Mm/dd/yy):	_//19
		ADMINISTRATIVE	
			DATE
	01	DATE CHART REVIEW COMPLETED	// 20
	02	FIRST CHART NOTE (Within one year PRECEDING index prostate cancer diagnosis date)	// 19
	03	LAST CLINICAL CHART NOTE	/
	DO NO	OT DATA ENTER THE INFORMATION AT T	THE BOTTOM OF THIS PAGE
Chart	Vol.#		eason not reviewed
		Reviewed: [1] Yes [2] No	
	_	Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
`.		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	
		Reviewed: [1] Yes [2] No	

					PD Study MR	#		
DEMOGRAF	PHICS					•	•	
	Marital Status at diagnostics 1 = Single 2 = Married 3 = Separated 4 = Divorced 5 = Widowed 7 = Unclear 8 = Not noted	osis		02= 03= 04= 50= 51= 70=	thnicity White Black Am. Indian Asian or Pacific Other Hispanic Unclear Not noted	Islander		
							T	4
	Height (at diagnosis)	feet/inches	/	Weight pounds	(at diagnosis)			
1	Code 9/99 for miss	sing height			Code 999 for m	nissing wei	ght	·
	onths BEFORE prostate		osis, was a dig 1=YES 2	gital recta =NO	l exam (DRE) p 7=Unclear = 8	erformed? 3 = Not no	oted	I
DATE								
Result								
Referral turologist			·					
AFTER the	date of diagnosis for pr	ostate cancer,	was a digital 1=YES 2	rectal exa	ım (DRE) perfoi 7≟Unclear	med? 8 = Not no	oted	
DATE								
Result						<u> </u>		
Referral urologist	. 1		,					
lf ı	more than 5 tests, record	d first three afte	er diagnosis a	nd last tw	o notations.			
PSA								
In the 12 r	nonths BEFORE prostat	e cancer diagno	osis, was a Pa	SA perfor 2=NO	med? 7=Unclear	8 = Not no	oted	l
DATE						ļ <u>.</u>		
PSA leve	el							
Referral Urologis			7=Unclear	8=Not	noted			

POST DIAGNOSIS PSA LEVELS	Work area to count PSA Lab Results						
Time since diagnosis	0 -3.99	4.0 - 9.99	≥ 10**	Total Number of PSAs in Time Period	Number of PSAs 0 - 3.99	Number of PSAs 4 - 9.99	Number of PSAs ≥ 10
0-12 months						•	
13-24 months							
25-36 months							
37-48 months				·			
49-60 months				· · · · · · · · · · · · · · · · · · ·			
Year 6-10							
Year 11-15					· · · · · ·		
Year 16-20							
Year 21-25						`	
Year 26+							

** ENTER DATE and LEVEL FOR ANY PSAs THAT EXCEED 10

DATE (Year in 4 digits)	LEVEL
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	·

PD Study MR #:							
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THE NEXT TWO PAGES REFER TO PROSTATE ACID PHOSPHATASE

In the 12 months BEFORE prostate cancer diagnosis, was an acid phosphatase level obtained?

1=YES 2=NO

7=Unclear

8 = Not noted

•

DATE			
Result			
Referral to urologist			

1=Yes

2=No

3=Test by Urologist

7=Unclear

8=Not noted

PD	Study	MR	#:							
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POST DIAGNOSIS ACID PHOSPHATASE LEVELS	Work area to count Acid Phosphatase Lab Results			Data Entry A	rea for Acid	Phosphatas	e Lab Results
Time since diagnosis	0 -0.8	0.81- 1.59	≥1.6**	Total Number of APs in Time Period	Number of APs 0 - 0.8	Number of APs 0.81-1.59	Number of APs ≥ 1.6
0-12 months							
13-24 months							•
25-36 months							
37-48 months							
49-60 months							
Year 6-10							·
Year 11-15		·					
Year 16-20							
Year 21-25	·						
Year 26+		<u> </u>					

** ENTER DATE and LEVEL FOR ANY PROSTATE ACID PHOSPHATASE LEVEL THAT EXCEEDS

DATE (Year in 4 digits)	LEVEL
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PD Study MR #:	
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NEEDLE BIOPSY

· BEFORE DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted		
In the 12 months BEFORE prostate cancer diagnosis, was a needle biopsy performed?			
		IF YES, what was the date?	
		IF YES, what was the result?	
In the 12 months BEFORE prostate cancer diagnosis, was a second needle biopsy performed?			
ponomo-		IF YES, what was the date?	
		IF YES, what was the result?	

AFTER DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted	
AFTER diagnosis of prostate cancer, was a needle biopsy performed?		
		IF YES, what was the date?
		IF YES, what was the result?
AFTER diagnosis of prostate cancer, was a second needle biopsy performed?		
		IF YES, what was the date?
		IF YES, what was the result?

	A	. NAD				•	
שץ	Study	mn	₩.	 	 		

BONE SCAN

BEFORE DIAGNOSIS

		1=YES 2=NO 7=Unclear 8=Not noted	
·	In the 12 months BEFORE prostate cancer diagnosis, was a bone scan performed?		
			IF YES, what was the date?
			IF YES, what was the result?
	In the 12 months BEFORE prostate cancer diagnosis, was a second bone scan performed?	·	
			IF YES, what was the date?
			IF YES, what was the result?

AFTER DIAGNOSIS

1 = YES 2 = NO 7 = Unclear 8 = Not noted	
AFTER diagnosis of prostate cancer, was a bone scan performed?	
•	IF YES, what was the date?
	IF YES, what was the result?
AFTER diagnosis of prostate cancer, was a second bone scan performed?	
	IF YES, what was the date?
	IF YES, what was the result?

D	Study	MR	#:							
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LYMPH NODE BIOPSY

BEFORE DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted	
In the 12 months BEFORE prostate cancer diagnosis, was a lymph node biopsy performed?	•	
		IF YES, what was the date?
		IF YES, what was the result?
		IF YES, how many nodes were biopsied?
		IF YES, how many nodes were positive?
In the 12 months BEFORE prostate cancer diagnosis, was a second lymph node biopsy performed?		
		IF YES, what was the date?
		IF YES, what was the result?
		IF YES, how many nodes were biopsied?
		IF YES, how many nodes were positive?

D	Study	MR	#:				
-				 -	 	 	

LYMPH NODE BIOPSY - Continued

AFTER DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted	
AFTER the diagnosis for prostate cancer, was a lymph node biopsy performed?		
		IF YES, what was the date?
		IF YES, what was the result?
		IF YES, how many nodes were biopsied?
		IF YES, how many nodes were positive?
AFTER the diagnosis for prostate cancer, was a second lymph node biopsy performed?		
		IF YES, what was the date?
		IF YES, what was the result?
		IF YES, how many nodes were biopsied?
		IF YES, how many nodes were positive?

ULTRASOUND OF THE PROSTATE BEFORE DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted	
In the 12 months BEFORE prostate cancer diagnosis, was a ultrasound of the prostate performed?		
		IF YES, what was the date?
		IF YES, what was the result?
In the 12 months BEFORE prostate cancer diagnosis, was a second ultrasound of the prostate performed?		
		IF YES, what was the date?
		IF YES, what was the result?

AFTER DIA	AGNOSIS		
		1=YES 2=NO 7=Unclear 8=Not noted	
	AFTER diagnosis of prostate cancer, was a ultrasound of the prostate performed?		
			IF YES, what was the date?
			IF YES, what was the result?
		•	
	AFTER diagnosis of prostate cancer, was a second ultrasound of the prostate performed?	î.	
20000	<u> </u>	l	IF YES, what was the date?
			IF YES, what was the result?

PD	Study	MR	#:		•			
	0.00			 		 	 	

MRI OF THE PROSTATE BEFORE DIAGNOSIS

	1=YES 2=NO 7=Unclear 8=Not noted	
In the 12 months BEFORE prostate cancer diagnosis, was a MRI of the prostate performed?		
],		IF YES, what was the date?
		IF YES, what was the result?
		,
In the 12 months BEFORE prostate cancer diagnosis, was a second MRI of the prostate performed?		
1	1	IF YES, what was the date?
		IF YES, what was the result?

AFTER DIAGNOSIS

AFIER DIA	AGNUSIS		
		1=YES 2=NO 7=Unclear 8=Not noted	
	AFTER diagnosis of prostate cancer, was a MRI of the prostate performed?		
			IF YES, what was the date?
			IF YES, what was the result?
	AFTER diagnosis of prostate cancer, was a second MRI of the prostate performed?		
		l	IF YES, what was the date?
			IF YES, what was the result?

PD	Study	/ MR	#:		 	 	

CAT SCAN OF THE PROSTATE BEFORE DIAGNOSIS

		1=YES 2=NO 7=Unclear 8=Not noted	
·	In the 12 months BEFORE prostate cancer diagnosis, was a CAT scan of the prostate performed?	·	
1			IF YES, what was the date?
			IF YES, what was the result?
	In the 12 months BEFORE prostate cancer diagnosis, was a second CAT scan of the prostate performed?		
			IF YES, what was the date?
			IF YES, what was the result?

AFTER DIAGNOSIS

AGNOSIS	1=YES 2=NO 7=Unclear 8=Not noted	·	
AFTER diagnosis of prostate cancer, was a CAT scan of the prostate performed?			
<u> </u>		IF YES, what was the date?	
		IF YES, what was the result?	
AFTER diagnosis of prostate cancer, was a second CAT scan of the prostate performed?			
1.5		IF YES, what was the date?	
		IF YES, what was the result?	

Was surgery performed for prostate treatment?

1=YES 2=NO 7=Unclear 8 = Not noted

DATE	TYPE	

10=TURP or transurethral resection of the prostate without lymph node dissection.

20=TURP or transurethral resection of the prostate with lymph node dissection.

30 = Subtotal/simple prostatectomy without dissection of lymph nodes

40 = Subtotal/simple prostatectomy with dissection of lymph nodes

50 = Radical or total prostatectomy without dissection of lymph nodes

60 = Radical or total prostatectomy with dissection of lymph nodes

70= Cystoprostatectomy, pelvic exeneration with or without dissection of lymph nodes

80= Surgery of regional or distance site or nodes ONLY

90= Prostatectomy, NOS, Surgery, NOS

5= Orchlectomy

RADIATION AFTER PROSTATE CANCER DIAGNOSIS

Was radiation given for prostate cancer treatment?

1=YES 2=NO 7=Unclear 8 = Not noted

Noted Complications			
Vendor (hospital or facility)		•	
Dose (Rads)			
Type 1=Cobalt 2=Linear 3=other 7=unclear/insuff info 8=Not noted			
Body Site 1=prostate 2=spine/back			
DATE mm/yy			

Was chemotherapy given for prostate cancer treatment?

8 = Not noted 7=Unclear 2=N0 1=YES DATE TYPE

HORMONE AFTER PROSTATE CANCER DIAGNOSIS

Was hormone treatment given for prostate cancer treatment? 1=YES 2=NO

8 = Not noted 7=Unclear START DATE STOP DATE

= Aminoglutethimide 1 = Aldactone 1 = Anadron

TYPE

1 = Casodex

1 = Cytadren 3 = Diethylstilbestrol

1= Cyproterone acetate 3= DES

3= estrogen

1= Glucoscoticolds/cortisone 2= leuprolide (Lupron) 3= Megace 1= nilutaminde 2= Lupron 3= Megestrol 2= Zoladex 1 = Flutamide 2= Goserelin

AFTER INITIAL PROSTATE CANCER TREATMENT,

Did cancer in the prostate recur?	1=YES	2=NO	7=Unclear	8 = Not noted	
Did metestatic cancer related to inital	1=YES	2=NO	7=Unclear	8 = Not noted	-
prostate cancer occur or recurr?					

OTHER SYMPTOMS / SIGNS / SIDE EFFECTS / COMPLICATIONS

				If after	
				diagnosis:	
	Noted before Dx	Noted before TUR	Noted AFTER DX	Was this treatment related?	Date First Noted
	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED 9=N/A	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED 9= N/A	wm/dd/yy
GI CONDITIONS					
Abdominal/pelvic pain - NOS					
Bowel Irritation				•	
Bowel obstruction					
Constipation					
Diarrhea					
GI upset -NOS					
Nausea or upset stomach				·	
Proctitis					
Ulcers					
Vomiting					
SKIN CONDITIONS					
Alopecia or hair loss					
Skin - burns			•		

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				If after diagnosis:	
	Noted before Dx	Noted before TUR	Noted AFTER Dx	Was this treatment related?	Date First Noted
	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED 9=N/A	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED	1=YES 2=NO 7=UNCLEAR 8=NOT NOTED 9= N/A	mm/dd/yy
Skin - rash, eczema,					
Skin - NOS					
GENERAL PROBLEMS					
Cachexla				·	
Fatigue, loss of energy, weakness	-				
Fever .					
Gynecomastla, enlarged breasts		•			·
Renal or kidney problems, NOS	-		·		
Weight loss			·	·	
RENAL / URINARY / SEXUAL					
Impotence/sexual dysfunction					
Loss of libido or sexual interest					
Urinary - dysuria				·	
Urinary - frequency					
Urinary - hematuria					

				If after diagnosis:	
	•			Was this	
	Noted before Dx	Noted before TUR	Noted AFTER Dx	reatment related?	Date First Noted
	1=YES	1 = YES	1=YES	1=YES	ww/pp/ww
		7=UNCLEAR 8=NOT NOTED	7=UNCLEAR 8=NOT NOTED	7=UNCLEAR 8=NOT NOTED	
		9=N/A		9= N/A	
Urinary - hesitancy					
Urinary - Incontinence					
Urinary - nocturia					
Urinary - painful urination			-		
Urinary - retention	•				
Urinary - other/NOS					

It is noted specifically in the medical record that the patient DOES NOT have the symptom. etc. It is noted specifically in the medical record that the patient DOES have the symptom, etc. NO YES

Code if a) it is reported specifically that unclear whether the symptom is present or b) the report itself is unclear as the whether the

patient has the symptom, etc.

No mention is made in the medical record as the whether the patient has or does not have the symptom, etc.
Record date symptom first noted in chart; use 99 for any part of date that is unclear. If symptom is "1", "7", "8", or "9", leave blank.

Recorded Date First

Not Noted

Unclear

COMORBID CONDITIONS

} ₽ 9	w-up												
THERAPY 1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. Info 8=Not noted	th or End of Follo					•							
PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info 8=Not stated	From Diagnosis to Death or End of Follow-up												
THERAPY 1 = therapy initiated 2 = Therapy changed 3 = No therapy 7 = Unclear/insuff, info 8 = Not noted	12 Months PRIOR to Diagnosis								•				
PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info 8=Not stated	12 Months PRIC												
CONDITION		AIDS	Alcohol Abuse	Anemia	ARTHRITIS	Arthritis, NOS	Inflammatory Arthritis	Polymyalgia Rheumatica	Rheumatold Arthritis	Back Pain Disease	CANCER (list type)		

	PRESENT	THERAPY	PRESENT	THERAPY
CONDITION	1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist, of or current 6=Review of system normal, infer absence 7=Unclear/insuff, info 8=Not stated	1=therapy Initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. Info 8=Not noted	2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist, of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info 8=Not stated	1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. info 8=Not noted
	12 Month	s PRIOR to Diagnosis	From Diagnosis to Dea	From Diagnosis to Death or End of Follow-up
Cerebrovascular Accident or disease or stroke				
Chėst (non-angina) pain				
Coagulopathy				
Deaf/NOS				
Diabetes				
EYE DISEASE			-	
Blind, NOS	•			
Cataracts				
Glaucoma				·
Macular Degeneration				
GASTROINTESTINAL DISEASE				
Cholecystitis				
Cholelithiasis				
Cirrhosis				

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THERAPY 1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff, info 8=Not noted	th or End of Follow							·					
PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info 8=Not stated	From Diagnosis to Death or End of Follow-up												
THERAPY 1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. info 8=Not noted	is PRIOR to Diagnosis					•							
PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info 8=Not stated	12 Months PRIC			;			•						
CONDITION		Diverticulitis	Diverticulosis	GI Hemorrhage	Hepatitis	Hatal Hemla	Inflammatory Bowel Disease OR Crohn's Disease	Liver Disease, NOS .	Peptic Ulcer Disease	Other Intestinal, stomach or GI problems, NOS	Ulcers	CARDIOVASCULAR OR HEART OR VASCULAR CONDITIONS	Angina or (Cardiac) Chest Paln

CONDITION	PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current hist. of or current absence 7=Unclear/insuff. Info 8=Not stated	THERAPY 1 = therapy initiated 2 = Therapy changed 3 = No therapy 7 = Unclear/insuff. info 8 = Not noted	PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence 7=Unclear/insuff. Info 8=Not stated	THERAPY 1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. Info 8=Not noted
	12 Mont	ns PRIOR to Diagnosis	From Diagnosis to Dea	From Diagnosis to Death or End of Follow-up
Arrhythmla				
Cardiac Arrest			·	
Congestive Heart Fallure (CHF)		•		
Deep Vein Thrombosis				·
Heart Disease NOS				
Myocardial Infarction			,	
Hypertension	•			
Thrombophlebitls				
Transient Ischemic Attack (TIA)		-		
Valvular Disease				
MENTAL OR NEUROLOGICAL DISEASE				
Alzheimer's Disease	-			

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### Skeletal in the condition noted specific report of no med. #### Table in the condition noted, no med an amagement mentioned and an amagement mentioned analysis	CONDITION	PRESENT 1=Current med. management	THERAPY	PRESENT 1=Current med. management	THERAPY
7 = Unclear/Insuff. Info 7 = Unclear/Insuff. Info 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 8 = Not stated 12 Months PRIOR to Diagnosis 12 Month		2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current absence	1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. Info 8=Not noted	2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence	1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. info 8=Not noted
asse LETAL Sint Disease or Skeletal Ithing from S S DR LUNG		Cont	OR to Diagnosis	7 = Unclear/insuff. Info 8 = Not stated From Diagnosis to Dea	th or End of Follow-up
ase ETAL oint Disease or Skeletal iting from S S DR LUNG	Dementia				
rase ETAL oint Disease or Skeletal ilting from S S DR LUNG	Depression				
sease rom NG	Other Dementia				
sease letal rom NG	Parkinson's disease				
	MUSCULOSKELETAL				
t or Skeletal sulting from OS	Degenerative Joint Disease (DJD)	-	·		
arthritis porosis porosis ————————————————————————————————————	Fracture				·
porosis Portion and Joint or Skeletal uel Joint or Skeletal Palen Resulting from a variant fr	Osteoarthritis		·		
ual Joint or Skeletal Pale Nomed Strommer Securiting from the southing from the southing from the security of th	Osteoporosis				
Pain NOS Pain NOS ysis 40NARY OR LUNG	Residual Joint or Skeletal Problem Resulting from Injury/Fall			·	
ysis Monary or Lung ASE	Other Paln NOS				
IONARY OR LUNG 4.SE	/sis				
	IONARY OR LUNG ASE				

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CONDITION	PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist. of or current 6=Review of system normal, infer absence	THERAPY 1=therapy initiated 2=Therapy changed 3=No therapy 7=Unclear/insuff. info 8=Not noted	PRESENT 1=Current med. management 2=Condition noted, specific report of no med. management, 3=Condition noted, no med mangement mentioned 4=History of condition 5=Condition noted, unknown if hist, of or current 6=Review of system normal, infer absence 7=Unclear/insuff. info	THERAPY 1 = therapy Initiated 2 = Therapy changed 3 = No therapy 7 = Unclear/insuff. info 8 = Not noted
	12 Months PRIC	12 Months PRIOR to Diagnosis	From Diagnosis to Dea	From Diagnosis to Death or End of Follow-up
Asthma				
Chronic Bronchitis				•
Chronic Obstructive Pulmonary Disease (COPD)	,			
Emphysema				
GENITOURINARY SYSTEM OR RENAL DISEASE				
Chronic Cystitis				
Kidney (renal) Fallure				
Nephritis				
Nephropathy				
Nephrosis				
Thyroid or Glandular Disorders				
Tinnitus or hearing problems				

Appendix B Celestine Kiki, M.D., M.P.H. Post Doctoral Fellow Prostate Cancer Screening and Mortality Study Progress Report

Celestine Kiki received her M.D. degree from the University of Benin in 1996. She completed and MPH in Epidemiology at the University of Oklahoma School of Public Health in 2001. She was recruited and joined the project on November 5, 2001.

The following are Project and Educational activities that She was engaged in:

She regularly attended the following seminars:

Public Health Cardiovascular Research Institute Social Epidemiology Research Division

She attended the following Software Training Classes listed below (offered by Department of Information Technology):

Jan. 14: Class 101-Microsoft PowerPoint Basic.

Jan. 23: Class 102-Microsoft PowerPoint Design.

Jan. 28: Class 103-Microsoft PowerPoint Advanced.

Feb. 4: Class 104-Using Word: Web&Publication Issues.

Feb. 18: Class 202-Photoshop, Scanning,&Fireworks.

Feb. 25: Class 203-Web Basics&HTML.

Mar. 6: Class 301-Dreamweaver.

Mar. 13: Class 401-All Tools.

May 30: Class 105-Word: Administrative Tasks.

May 8: Class 106-Excel Basics.

June 12: Class 107-Access Basics.

July 3: Class 204-Photoshop Intermediate.

She wrote and submitted to the Department of Defense on June 18, 2002 a proposal entitled, "the association talcum powder use, coffee and alcohol consumption and ovarian cancer among women in Metropolitan Atlanta." This was completed in consultation with Drs Asal, (P.I.) Patello P {rofessor of OBGYN and Dr. Lee Caplan (Associate Professor of Community Health and Preventive Medicine (Epidemiologist)

Since June 24, she has been involved performing chart abstractions for the prostate cancer study. In addition, she is involved in the study of risk factors of ovarian cancer in Johanesburg (South Africa) for Morehouse of Medicine Department of Pediatrics South African Pediatric Elective.

She registerd and plans to attend the Americal Public Health Association Annual Meeting in Philadelphia in November, 2002.